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10/821,127	04/07/2004	Kenneth J. Micklash II	36-003210US	8255
22798 7590 06/07/2007 QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			EXAMINER AKRAM, IMRAN	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/821,127	Applicant(s) MICKLASH ET AL.	
	Examiner Imran Akram	Art Unit 1709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-96 is/are pending in the application.
- 4a) Of the above claim(s) 46 and 82-96 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 and 47-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-96 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/12/04, 11/29/04, 12/27/04, 08/07/06.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-45 and 47-81, drawn to a material removal head or a multi-well plate processing system, classified in class 422, subclass 99.
 - II. Claims 46 and 82, drawn to a dispense head or dispensing system, classified in class 222, subclass 263.
 - III. Claims 83-96, drawn to a method of removing material, classified in class 422, subclass 100.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.
3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product: the same product can be used as a dispenser or mixer.

4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product: the same product can be used as a removal head.

5. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

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over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. During a telephone conversation with Chris Sappenfield on 5/15/07 a provisional election was made with traverse to prosecute the invention I, claims 1-45 and 47-81. Affirmation of this election must be made by applicant in replying to this Office action. Claims 46 and 82-96 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 9, 12, 13, 15-18, 20, 32-34, 44, and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Spencer (US 4,791,821).

10. Regarding claim 1, Spencer discloses an injection means (Figure 3, 28) comprising at least one tip (31) that comprises at least one vent opening (14), at least

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one inlet (13), at least one outlet (2), which inlet communicates with the outlet (3) and is structured that when the inlet is disposed proximal to a selected well from which a material is to be removed, the top forms a barrier (32) between the selected well (33) and at least one adjacent well. While the reference discloses an injection means, the injector is structured as to be capable of removing liquid and thus serves as a removal head. Were the outlet to be connected to a negative pressure source, air would be drawn through the vent opening and into the inlet, thereby noninvasively removing material from the selected well while the barrier prevents cross-contamination of the adjacent well.

11. Regarding claim 2, Spencer discloses a tip structured such that when the inlet is disposed proximal to the selected well, the tip forms a barrier (33) between the selected well (33) and all adjacent wells.

12. Regarding claim 9, Spencer discloses a tip structured to noninvasively remove fluidic material from the selected well. See Figure 1: Were the outlet to be connected to a negative pressure source, air would be drawn through the vent opening and into the inlet, thereby noninvasively removing material from the selected well while the barrier prevents cross-contamination of the adjacent well.

13. Regarding claim 12, Spencer discloses a tip wherein the cross-sectional area of the tip is less than the cross-sectional area of at least one well disposed in a multi-well plate. See Figure 3.

14. Regarding claim 13, Spencer discloses a tip comprising at least one acute edge. See Figure 3.

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15. Regarding claim 15, Spencer discloses a tip comprising angled surfaces that mate with the sides of the selected well. See Figure 3.

16. Regarding claim 16, Spencer discloses one angled surface comprising of a vent opening that allows air passage into the selected well. See Figure 3.

17. Regarding claim 17, Spencer discloses a vent opening (14) that is bound by the acute edge. See Figure 3.

18. Regarding claim 18, Spencer discloses a tip comprising a seal material around the tip (barrier 32).

19. Regarding claim 20, Spencer discloses a vent opening (14) formed between the seal material (32) and one side of the tip, allowing for air passage into the selected well.

20. Regarding claim 32, Spencer discloses a material removal head (28) comprising at least one vent opening (14), at least one inlet (13), at least one outlet (2), which inlet communicates with the outlet (3). Were the outlet to be connected to a negative pressure source, air would be drawn through the vent opening and into the inlet, thereby noninvasively removing material from the selected well while the barrier prevents cross-contamination of the adjacent well. The material removal head surface is structured that when the inlet is disposed proximal to a selected well from which a material is to be removed, the barrier (32) forms a seal between the selected well (33) and at least one adjacent well.

21. Regarding claim 33, Spencer discloses a surface of the material removal head (28) being substantially flat.

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22. Regarding claim 34, Spencer discloses an acute edge **15** that separates inlet **13** from vent **14**.

23. Regarding claim 44, Spencer discloses a material removal head (**28**) comprising at least one vent opening (**14**), at least one inlet (**13**), at least one outlet (**2**), which inlet communicates with the outlet (**3**). Were the outlet to be connected to a negative pressure source, air would be drawn through the vent opening and into the inlet, thereby noninvasively removing material from the selected well while the barrier prevents cross-contamination of the adjacent well. The material removal head surface is structured that when the inlet is disposed proximal to a selected well from which a material is to be removed, the barrier (**32**) mates with the selected well (**33**).

24. Regarding claim 45, Spencer discloses a material removal head (**28**) comprising at least one vent opening (**14**), at least one inlet (**13**), and at least one outlet (**2**), which inlet communicates with the outlet (**3**). The inlet disclosed comprises a cross-sectional dimension that is less than a first cross-sectional dimension of at least one well disposed in at least one multi-well plate and a second cross-sectional dimension that substantially corresponds to at least a segment of a length of at least one line of wells disposed in a multi-well plate as this is circumstantial to the sizes of the wells. Were the outlet to be connected to a negative pressure source, air would be drawn through the vent opening and into the inlet, thereby noninvasively removing material from the selected well while the barrier prevents cross-contamination of the adjacent well. The material removal head surface is structured that when the inlet is disposed proximal to a

selected well from which a material is to be removed, the barrier (32) forms a seal between the selected well (33) and at least one adjacent well.

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

26. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

27. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

28. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer as applied to claim 1 above, and further in view of Koizumi (US 4,734,261).

29. Spencer does not disclose the limitations of claim 3. Koizumi, however, discloses a tip with a resilient coupling (see Figure 5C). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use this method to vary the distance between two tips as their purpose is the same: to accommodate wells over varying spacing.

30. Claims 4-8, 10, 11, 14, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer as applied to claim 1 above, and further in view of Lancaster (US 3,650,306).

31. Spencer does not disclose the limitations of claim 4. Lancaster, however, discloses a material removal head comprising multiple tips (see Figure 1, 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple tips instead of one when there are multiple wells to remove material from. Such multi-tip removal heads are commonly known in the art.

32. Spencer does not disclose the limitations of claim 5. Lancaster, however, discloses a material removal head comprising at least one manifold (figure 7, 100). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a manifold for multiple input/outputs as this is their very purpose. Manifolds in removal heads are commonly known in the art.

33. Spencer does not disclose the limitations of claim 6. Lancaster, however, discloses a material removal head comprising of at least two tips (27), wherein the inlet

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of the tips are spaced at a distance that corresponds between at least two wells (52) disposed in a multi-well plate (50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose an appropriate distance between the tips for the appropriate wells with which they will function in conjunction with. The spacing of the tips is circumstantial upon the spacing of the wells—which is not a limitation of this claim.

34. Regarding claim 7, neither Spencer nor Lancaster discloses the specific tip spacing distances. It would have been obvious to one having ordinary skill in the art at the time the invention was made to space the tips at any of these metric values according to the spacing of the wells.

35. Regarding claim 8, Spencer discloses a material removal head structured to noninvasively removed materials from a plurality of multi-well plates, but not simultaneously. Lancaster, however, discloses removing material from multiple wells at the same time (column 1, lines 56-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to allow removal of multiple heads simultaneously when there are multiple tips from which to draw. Lancaster is capable of doing just this, as are many removal heads known in the art.

36. Spencer does not disclose the limitations of claim 10. Lancaster, however, discloses tips comprising a cross-sectional shape that is circular (See Figure 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a circular shape as it is a matter of choice (see *In re Dailey*, 357 F.2d 669,

149 USPQ 47 (CCPA 1966)). The shape of the tip would be chosen based upon the shape of the well.

37. Regarding claim 11, Spencer discloses a material removal head structured to noninvasively remove materials from a plurality of multi-well plates. Lancaster, however, discloses tips structured to remove materials from a multi-well plate comprising 96 wells (see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to structure the multiple tips in any numerical order for an appropriate number of wells. There are well plates known in the art to have various numbers of wells.

38. Spencer does not disclose the limitations of claim 14. Lancaster, however, discloses a mounting bracket that mounts the material head to at least one device component (see figure 1, **36**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a bracket to mount the removal head to the device component being used in this apparatus. This is commonly done in the art.

39. Spencer does not disclose the limitations of claim 21. Lancaster, however, discloses a plurality of tips that comprise a footprint that corresponds to a footprint of one line of wells (see Figure 1, **27** and **52**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form a footprint with an array of tips because this needs to be done when effectively removing from multiple, predetermined wells and so is often done in the art.

40. Spencer does not disclose the limitations of claim 22. Lancaster, however, discloses the same number of spacing between the tips as between the wells (see

Figure 1, 27 and 52). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a number of tips that is a multiple of the number of wells as the wells because this needs to be done when effectively removing from multiple, predetermined wells and so is often done in the art.

41. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer as applied to claim 18 above, and further in view of Haxo (US 6,143,252).

42. Spencer does not disclose the limitations of claim 19. Haxo does, however, disclose a suitable seal made of rubber (see column 5, lines 56-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use rubber as a sealing material because it is a common material for doing just that in the art.

43. Claims 23-28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer as applied to claim 1 above, and further in view of Lancaster (US 3,650,306).

44. Spencer does not disclose the negative pressure source of claim 23. Lancaster, however, discloses a negative pressure means for aspirating liquid (see column 6, lines 52-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a negative pressure source for material removal means as it is a commonly known method to aspirate fluids. Attaching any negative pressure source to the outlet tube (2) of Spencer would result in the removal of the fluids from well 33.

45. Spencer does not disclose the details of claim 24. Lancaster, however, discloses a negative pressure means for aspirating liquid that is integral with the removal head

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(see column 6, lines 52-66 and figure 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the pressure source integral with the removal head as it will be creating the vacuum to remove the liquid directly above it. Also, the pressure source is one of the device components the removal head is bracketed to.

46. Regarding claim 25, neither Spencer nor Lancaster discloses a pump as the negative pressure source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to do so, however, as a pump is a common means in the art to create a vacuum or withdrawal pressure.

47. Regarding claim 26, neither Spencer nor Lancaster discloses the specific values of negative pressure or the flow rate created by the source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an appropriate value for pressure and thus flow rate, as this is a parameter necessary for aspirating the appropriate aliquot of material.

48. Regarding claim 27, Spencer discloses a tube operably connected to the outlet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a negative pressure source for material removal means, as it is a commonly known method to aspirate fluids. Attaching any negative pressure source to the outlet tube (2) of Spencer would result in the removal of the fluids from well 33.

49. Regarding claim 28, neither Spencer nor Lancaster discloses the removal device being hand-held. It would have been obvious to one having ordinary skill in the art at the

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time the invention was made to construct the removal head to be hand-held as there are countless embodiments of hand held pipettes and aspirating devices in the art.

50. Spencer does not disclose the details of claim 30. Lancaster, however, discloses a valve (**188**) for regulating pressure flow from the negative pressure source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the removal head to use a valve with the negative pressure source, as this is the common means to regulate pressure flow and aspiration flow will need to be controlled in order to be effective.

51. Spencer does not disclose the details of claim 31. Lancaster, however, discloses a solenoid valve (**188**) for regulating pressure flow from the negative pressure source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the removal head to use a solenoid valve with the negative pressure source, as this is a common means to regulate pressure flow and aspiration flow will need to be controlled in order to be effective.

52. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer and Lancaster as applied to claim 23 above, and further in view of McCandless (US 5,935,523).

53. Neither Spencer nor Lancaster discloses a trap head structured to trap waste material. McCandless disclose a material removal head attached to a trap to trap vent liquid (see column 9, lines 57-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a trap to trap aspirated liquids as this is often done in the art to trap unwanted aspirates.

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54. Claims 35-40, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer as applied to claim 32 above, and further in view of Lancaster (US 3,650,306).

55. Spencer does disclose the negative pressure source of claim 35. Lancaster, however, discloses a negative pressure means for aspirating liquid (see column 6, lines 52-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a negative pressure source for material removal means, as it is a commonly known method to aspirate fluids. Attaching any negative pressure source to the outlet tube (2) of Spencer would result in the removal of the fluids from well 33.

56. Spencer does not disclose the details of claim 36. Lancaster, however, discloses a negative pressure means for aspirating liquid that is integral with the removal head (see column 6, lines 52-66 and figure 7). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the pressure source integral with the removal head as it will be creating the vacuum to remove the liquid directly above it. Also, the pressure source is one of the device components the removal head is bracketed to.

57. Regarding claim 37, neither Spencer nor Lancaster discloses a pump as the negative pressure source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to do so, however, as a pump is a common means in the art to create a vacuum or withdrawal pressure.

58. Regarding claim 38, neither Spencer nor Lancaster discloses the specific values of negative pressure or the flow rate created by the source. It would have been obvious

to one having ordinary skill in the art at the time the invention was made to use an appropriate value for pressure and thus flow rate, as this is a common parameter within in to work.

59. Regarding claim 39, Spencer discloses a tube operably connected to the outlet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a negative pressure source for material removal means, as it is a commonly known method to aspirate fluids. Attaching any negative pressure source to the outlet tube (2) of Spencer would result in the removal of the fluids from well 33.

60. Regarding claim 40, neither Spencer nor Lancaster discloses the removal device being hand-held. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the removal head to be hand-held as there are countless embodiments of hand held pipettes and aspirating devices in the art.

61. Spencer does not disclose the details of claim 42. Lancaster, however, discloses a valve (188) for regulating pressure flow from the negative pressure source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the removal head to use a valve with the negative pressure source, as this is the common means to regulate pressure flow and aspiration flow will need to be controlled in order to be effective.

62. Spencer does not disclose the details of claim 43. Lancaster, however, discloses a solenoid valve (188) for regulating pressure flow from the negative pressure source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the removal head to use a solenoid valve with the negative

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pressure source, as this is a common means to regulate pressure flow and aspiration flow will need to be controlled in order to be effective.

63. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer and Lancaster as applied to claim 35 above, and further in view of McCandless (US 5,935,523).

64. Neither Spencer nor Lancaster discloses a trap head structured to trap waste material. McCandless disclose a material removal head attached to a trap to trap vent liquid (see column 9, lines 57-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a trap to trap aspirated liquids as this is often done in the art to trap unwanted aspirates.

65. Claims 47, 48, 50-66, 72, 73, and 75-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer (US 4,791,821) in view of Lancaster (US 3,650,306).

66. Regarding claim 47, Spencer discloses a material removal head (Figure 3, **28**) comprising at least one tip (**31**) that comprises at least one vent opening (**14**), at least one inlet (**13**), at least one outlet (**2**), which inlet communicates with the outlet (**3**) and is structured that when the inlet is disposed proximal to a selected well from which a material is to be removed, the top forms a barrier (**32**) between the selected well (**33**) and at least one adjacent well. Were the outlet to be connected to a negative pressure source, air would be drawn through the vent opening and into the inlet, thereby noninvasively removing material from the selected well while the barrier prevents cross-contamination of the adjacent well. Spencer does not, however, disclose a positioning component that is structured to position one or more multi-well plates relative to the

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removal head or at least one dispensing component that is structured to dispense one more materials into one or more wells of one or more multi-well plates.

67. Lancaster discloses a system comprising a carrier plate **40** for positioning the multi-well plates and a dispenser **26**. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the removal head of Spencer to the dispenser/positioner of Lancaster if it was desired for the removal head to be of materially different design than the dispensing head. The removal head of Spencer is structured to noninvasively withdraw material while the dispensing component of Lancaster is not.

68. Spencer does not disclose the limitations of claim 48. Lancaster, however, discloses a material removal head comprising multiple tips. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple tips instead of one when there are multiple wells to remove material from. Such multi-tip removal heads are commonly known in the art.

69. Regarding claim 50, Spencer discloses a tip capable of mating with the selected well.

70. Spencer does not disclose the negative pressure source of claim 51. Lancaster, however, discloses a negative pressure means for aspirating liquid (see column 6, lines 52-66) as well as a material removal head comprising at least one manifold (figure 7, **100**). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a negative pressure source for material removal means as it is a commonly known method to aspirate fluids. Attaching any negative pressure source

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to the outlet tube (2) of Spencer would result in the removal of the fluids from well 33.

Manifolds' purpose is for multiple input/outputs and is commonly known in the art.

71. Spencer does not disclose the limitations of claim 52. Lancaster, however, discloses a material removal head comprising at least one manifold (figure 7, 100). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a manifold for multiple input/outputs, as this is their very purpose.

Manifolds in removal heads are commonly known in the art.

72. Spencer does not disclose the limitations of claim 53. Lancaster, however, discloses a material removal head comprising of at least two tips (27), wherein the inlet of the tips are spaced at a distance that corresponds between at least two wells (52) disposed in a multi-well plate (50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to choose an appropriate distance between the tips for the appropriate wells with which they will function in conjunction with. The spacing of the tips is circumstantial upon the spacing of the wells—which is not a limitation of this claim.

73. Regarding claim 54, neither Spencer nor Lancaster discloses the specific tip spacing distances. It would have been obvious to one having ordinary skill in the art at the time the invention was made to space the tips at any of these metric values according to the spacing of the wells.

74. Regarding claim 55, Spencer discloses a material removal head structured to noninvasively removed materials from a plurality of multi-well plates, but not simultaneously. Lancaster, however, discloses removing material from multiple wells at

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the same time (column 1, lines 56-64). It would have been obvious to one having ordinary skill in the art at the time the invention was made to allow removal of multiple heads simultaneously when there are multiple tips from which to draw. Lancaster is capable of doing just this, as are many removal heads known in the art.

75. Regarding claim 56, Spencer discloses a tip structured to noninvasively remove fluidic material from the selected well.

76. Spencer does not disclose the limitations of claim 57. Lancaster, however, discloses tips comprising a cross-sectional shape that is circular (See Figure 9). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a circular shape as it is a matter of choice (see *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)). The shape of the tip would be chosen based upon the shape of the well.

77. Regarding claim 58, Spencer discloses a material removal head structured to noninvasively remove materials from a plurality of multi-well plates. Lancaster, however, discloses tips structured to remove materials from a multi-well plate comprising 96 wells (see figure 1). It would have been obvious to one having ordinary skill in the art at the time the invention was made to structure the multiple tips in any numerical order for an appropriate number of wells. There are well plates known in the art to have various numbers of wells.

78. Regarding claim 59, Spencer discloses a tip wherein the cross-sectional area of the tip is less than the cross-sectional area of at least one well disposed in a multi-well plate. See Figure 3.

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79. Regarding claim 60, Spencer discloses a tip comprising at least one acute edge.

See Figure 3.

80. Regarding claim 61, Spencer discloses a tube operably connected to the outlet. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a negative pressure source for material removal means as it is a commonly known method to aspirate fluids. Attaching any negative pressure source to the outlet tube (2) of Spencer would result in the removal of the fluids from well 33.

81. Regarding claim 62, neither Spencer nor Lancaster discloses a pump as the negative pressure source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to do so, however, as a pump is a common means in the art to create a vacuum or withdrawal pressure.

82. Regarding claim 63, neither Spencer nor Lancaster discloses the specific values of negative pressure or the flow rate created by the source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an appropriate value for pressure and thus flow rate, as this is a parameter necessary for aspirating the appropriate aliquot of material.

83. Spencer does not disclose the limitations of claim 64. Lancaster, however, discloses a dispensing component comprising at least one dispenser that aligns with one or more wells disposed in one or more multi-well plates when the multi-well plates are disposed proximal to the dispenser (see column 3, lines 13-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the dispensing head of Lancaster to the removal head of Spencer if it was desired for

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the removal head to be of materially different design than the dispensing head. The removal head of Spencer is structured to noninvasively withdraw material while the dispensing component of Lancaster is not.

84. Spencer does not disclose the limitations of claim 65. Lancaster, however, discloses a dispensing component structured to dispense one or more fluidic materials (see column 1, lines 55-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the dispensing head of Lancaster to the removal head of Spencer if it was desired for the removal head to be of materially different design than the dispensing head. The removal head of Spencer is structured to noninvasively withdraw material while the dispensing component of Lancaster is not.

85. Spencer does not disclose the limitations of claim 66. Lancaster, however, discloses a dispensing component structured to dispense one or more fluidic materials simultaneously (see column 1, lines 55-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the dispensing head of Lancaster to the removal head of Spencer if it was desired for the removal head to be of materially different design than the dispensing head. The removal head of Spencer is structured to noninvasively withdraw material while the dispensing component of Lancaster is not.

86. Spencer does not disclose the limitations of claim 72. Lancaster, however, discloses a translocation component structured to translocate a multi-well plate for removal, positioning, and dispensing (see column 3, lines 13-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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87. Spencer does not disclose the limitations of claim 73. Lancaster, however, discloses a washing component to wash at least a portion of the removal or dispensing components (see column 2, lines 7-13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the removal head of Spencer to the dispenser/positioner of Lancaster if it was desired for the removal head to be of materially different design than the dispensing head. The system of Lancaster includes a washing component and Spencer does not. Washing components are commonly known in the art to clean out dispenser/removal heads after use and prior to use.

88. Spencer does not disclose the limitations of claim 75. Lancaster, however, discloses a translocation component structured to move a multi-well plate relative to a removal component (see column 3, lines 13-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the removal head of Spencer to the dispenser/positioner of Lancaster if it was desired for multiple well plates to be filled or emptied—a common procedure in the art

89. Spencer does not disclose the limitations of claim 76. Lancaster, however, discloses a plurality of tips that comprise a footprint that corresponds to a footprint of one line of wells. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form a footprint with an array of tips because this needs to be done when effectively removing from multiple, predetermined wells and so is often done in the art.

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90. Spencer does not disclose the limitations of claim 77. Lancaster, however, discloses the same number of spacing between the tips as between the wells. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a number of tips that is a multiple of the number of wells as the wells because this needs to be done when effectively removing from multiple, predetermined wells and so is often done in the art.

91. Spencer does not disclose the limitations of claim 78. Lancaster, however, discloses a valve (188) for regulating pressure flow from the negative pressure source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the removal head to use a valve with the negative pressure source, as this is the common means to regulate pressure flow and aspiration flow will need to be controlled in order to be effective.

92. Spencer does not disclose the limitations of claim 79. Lancaster, however, discloses a solenoid valve (188) for regulating pressure flow from the negative pressure source. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the removal head to use a solenoid valve with the negative pressure source, as this is a common means to regulate pressure flow and aspiration flow will need to be controlled in order to be effective.

93. Spencer does not disclose the limitations of claim 80. Lancaster, however, discloses a control means for the operation of the equipment operably connected to a component of the system (see column 2, lines 1-5). It would have been obvious to one

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having ordinary skill in the art at the time the invention was made to add a control means to Spencer has this is the most common method to automate a process.

94. Regarding claim 81, neither Spencer nor Lancaster discloses a computer control means. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a computer as a control means as this is the most common method with which to do so in almost all art.

95. Claim 49 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer and Lancaster as applied to claim 47 above, and further in view of Koizumi (US 4,734,261).

96. Neither Spencer nor Lancaster discloses the limitations of claim 49. Koizumi, however, discloses a tip with a resilient coupling. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use this method to vary the distance between two tips as their purpose is the same: to accommodate wells over varying spacing.

97. Neither Spencer nor Lancaster discloses the limitations of claim 67. Koizumi, however, discloses a dispenser that can be angled relative to a Z-axis (see Figure 5C). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the angling abilities of Koizumi in an attempt to dispense onto the side walls of the wells.

98. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer and Lancaster as applied to claim 47 above, and further in view of McCandless (US 5,935,523).

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99. Neither Spencer nor Lancaster discloses a trap head structured to trap waste material. McCandless disclose a material removal head attached to a trap to trap vent liquid (see column 9, lines 57-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a trap to trap aspirated liquids as this is often done in the art to trap unwanted aspirates.

100. Claims 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer and Lancaster as applied to claim 47 above, and further in view of Ruddock (US 2003/0215360 A1).

101. Regarding claim 69, Lancaster discloses translocation means, but not by robotic gripping means. Ruddock discloses a device for translocating multi-well plates by means of gripping jaws (see paragraph 59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to move the plates of Lancaster by the means of Ruddock as they both serve to translocate a multi-well plate.

102. Regarding claim 70, Lancaster discloses the replacement of multi-well plates, but not a storage means for them. Ruddock discloses a well plate storage rack 108. It would have been obvious to one having ordinary skill in the art at the time the invention was made to store the plates of Lancaster by the means of Ruddock as they both serve to translocate multi-well plates.

103. Claims 71 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spencer and Lancaster as applied to claim 47 above, and further in view of Stylli (US 6,468,800 B1).

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104. Neither Lancaster nor Spencer discloses an incubator. Stylli, however, discloses a system for removing, transporting, and dispensing that includes an incubator (see figure 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include an incubator in the system as a means to regulate temperature if that is so desired. Incubators are commonly found in conjunction with multi-well plates for this same purpose.

105. Neither Lancaster nor Spencer discloses a detector. Stylli, however, discloses a system for removing, transporting, and dispensing that includes a detector (see figure 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a detector in the system to detect the status and contents of the materials in the system. Detectors are commonly found in conjunction with multi-well plates for this same purpose.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Imran Akram whose telephone number is 571-270-3241. The examiner can normally be reached on 8-6 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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